Paper No. 25

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte ROGER COLEMAN and SUSAN G. STUART

Appeal No. 2003-1168
Application No. 09/467,100

ON BRIEF

Before, WILLIAM F. SMITH, MILLS and GRIMES, Administrative Patent Judges.

MILLS, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. §134 from the examiner's final rejection of claims 30-40, which are all of the claims pending in this application.

Claims 30, 36 and 37 are illustrative of the claims on appeal and read as follows:

30. An isolated polynucleotide encoding a polypeptide selected from the group consisting of:
a) an amino acid sequence of SEQ ID NO:2, and
b) a fragment of an amino acid sequence of SEQ ID NO:2, wherein said fragment has kinase activity.

36. An isolated polynucleotide comprising a polynucleotide sequence selected from the group consisting of:

a) the polynucleotide sequence of SEQ ID NO:1,

b) a naturally occurring polynucleotide sequence having greater than 92% sequence identity to the polynucleotide sequence of SEQ ID NO:1,

c) a polynucleotide sequence complementary to a),

d) a polynucleotide sequence complementary to b), and

e) an RNA equivalent of a)-d).

37. A method for detecting a target polynucleotide in a sample, said target polynucleotide having a sequence of a polynucleotide of claim 36, the method comprising:

a) hybridizing the sample with a probe comprising at least 16 contiguous nucleotides comprising a sequence complementary to said target polynucleotide in the sample, and which probe specifically hybridizes to said target polynucleotide, under conditions whereby a hybridization complex is formed between said probe and said target polynucleotide or fragments thereof, and

b) detecting the presence or absence of said hybridization complex, and optionally, if present, the amount thereof.

The prior art references cited by the examiner are:

Coleman et al. (Coleman) 5,914,393 June 22, 1999

Silvennoinen et al. (Silvennoinen), "Structure of the murine Jak2 protein-tyrosine kinase and its role in interleukin 3 signal transduction," Proc. Nat. Acad. Sci., Vol. 90, pp. 8429-8433 (1993)

Grounds of Rejection

Claims 36-40 stand rejected under 35 U.S.C. §112, first paragraph, as lacking enablement throughout the claim scope.

Claims 36-40 stand rejected under 35 U.S.C. §112, first paragraph, for lack of written description of variants (alleles) of SEQ ID NO:1.

Claims 36-40 stand rejected under 35 U.S.C. §112, first paragraph, for lack of written description of a naturally occurring polynucleotide sequence having greater than 92% sequence identity to the polynucleotide sequence of SEQ ID NO:1.

Claims 37-40 stand rejected under 35 U.S.C. §103(a) for obviousness over Silvennoinen.

Claims 30-40 stand rejected for obviousness-type double patenting.

We affirm the double patenting rejections. We affirm the rejection of claims 36-40 under 35 U.S.C. §112, first paragraph, for lack of written description of a naturally occurring polynucleotide sequence having greater than 92% sequence identity to the polynucleotide sequence of SEQ ID NO:1. We do not reach the lack of enablement and obviousness rejections. We do not reach the rejection of claims 36-40 under 35 U.S.C. §112, first paragraph, for lack of written description of variants (alleles) of SEQ ID NO:1.

Claim Grouping

According to appellants, the claims stand or fall together for each rejection. Brief, page 5. We treat the independent claim of each rejection as representative. 37 CFR §1.192(c)(7) (2002) (now 37 CFR § 41.37(c)(1)(vii)).

DISCUSSION

Obviousness-type Double Patenting

Claims 30-40 stand rejected for obviousness-type double patenting.

The examiner finds claims 30-36 unpatentable for obviousness-type double patenting over claims 1-3 of U.S. Patent No. 5,914,393, and claims 37-40 unpatentable for obviousness-type double patenting over claim 10 of U.S. Patent No. 5,914,393.

Answer, pages 10-11.

Appellants indicate (Appeal Brief, page 29) that they are willing to file a terminal disclaimer to address these rejections.

No terminal disclaimer has been filed to date in this application. Answer, page 26. Thus we summarily affirm the rejections of the claims for obviousness-type double patenting.

35 U.S.C. § 112, first paragraph

Claims 36-40 stand rejected under 35 U.S.C. § 112, first paragraph as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors has possession of the invention at the time the application was filed.

The examiner argues that the phrase "greater than 92% identity" is new matter that is not supported by the original specification.

Appellants point to the specification, page 3, lines 29-36 in support of this claim language. The specification page 3, states:

> [t]he assembled nucleotide sequence (SEQ ID NO:1), hjak2, encodes the polypeptide (SEQ ID NO:2), HJAK2 (SEQ ID NO:2). Computer search and alignment of the full length amino acid sequence showed HJAK2 has 92% similarity to murine Jak2 kinase (MUSPTK1; GenBank GI 409584; Wilks AF (1998) Proc. Nat. Acad. Sci. 86:1603-7) which in turn has 96% sequence similarity with human Jak1 kinase.

We are not persuaded by appellants' argument. Claim 36 (b) states, "b) a naturally occurring polynucleotide sequence having greater than 92% sequence identity to the polynucleotide sequence of SEQ ID NO:1." The specification, however, describes that alignment of the full length amino acid sequence **(SEQ ID NO: 2)** showed HJAK2 has 92% similarity to murine Jak2 kinase. We find no indication by appellants, or in the present specification, that they intended to claim or had possession of a polynucleotide sequence which has 92% sequence identity to **SEQ ID NO: 1,** as only the amino acid sequence **(SEQ ID NO: 2)** was described as having 92% identity to the murine Jak2 protein.

Appellants further argue that "the inventors were aware of the Wilks murine Jak2 kinase, which has 92% similarity to the amino acid sequence of SEQ ID NO:2. Hence it is axiomatic that the present inventors considered naturally occurring polynucleotide sequences having greater than 92% sequence identity to the polynucleotide sequence of SEQ ID NO:1 as part of their invention, *i.e.*, those naturally occurring polynucleotide sequences which were not part of the prior art." Brief, page 26. We are not persuaded by this argument. It remains that appellants have failed to describe polynucleotides having 92% identity to SEQ ID NO:1. Moreover, due to the degeneracy of the genetic code and the potential for introns in a genomic polynucleotide sequence we find no specific correlation between the percent identity in an amino acid sequence and any relative or axiomatic percent identity in a polynucleotide sequence.

We affirm the rejection of claims 36-40 for lack of written description in the specification as filed.

The above rejections dispose of all the claims before us. We do not reach the rejections of the claims for obviousness, lack of enablement and lack of written description of the allelic variants of SEQ ID NO:1. Answer, page 7.

Other Issue

Should prosecution of the application continue upon the filing of a terminal disclaimer in the application, we direct the examiner's attention to the following with respect to claim 36.

The normal meaning of "polynucleotide" is a polymer made up of nucleotides. Nucleotides are made up of a purine or pyrimidine base joined to a sugar residue (deoxyribose in DNA, ribose in RNA) and a phosphate group. Thus, according to normal meaning, part (b) of claim 36 would encompass both DNA and RNA. Read however in light of the rest of the claim and the specification, the scope of the claim seems unclear.

SEQ ID NO:1 is a DNA sequence since it contains thymine (T) residues. The equivalent RNA sequence would have uracil (U) in place of thymidine. It is unclear from reading the specification whether T and U would be considered to be "identical" residues in computing whether a given polynucleotide had 92% identity to SEQ ID NO:1.

Next, if part (b) of claim 36 is intended to include both DNA and RNA, then part (e) of the claim is entirely superfluous. That is, there would be no need for part (e) directed to RNA equivalents unless parts (a)-(d) are intended to be limited to DNA, rather than encompassing both DNA and RNA.

If we assume that the term "polynucleotide" is a synonym for DNA, construing part (b) of claim 36 as limited to DNA has its own problems. If part (b) of claim 36 were construed to encompass naturally occurring DNA sequences, that part of the claim would likely define a compound that does not exist.

The DNA sequence shown in the specification for SEQ ID NO: 1 is a cDNA sequence. cDNAs are not naturally occurring. They are laboratory-made DNA copies of naturally occurring messenger RNA (mRNA) sequences. The only naturally occurring DNA sequence that encodes the protein of SEQ ID NO:1 is a genomic sequence. That genomic sequence is then transcribed by the cell into an RNA equivalent that is processed and eventually translated into the polypeptide of SEQ ID NO:2. The processing steps required to generate an mRNA from a genomic DNA include removal of intervening sequences, or introns.

Virtually all human genes include introns. Those skilled in the art would expect that a naturally occurring gene encoding the polypeptide of SEQ ID NO:2 would include and be interrupted by several introns. As a result those skilled in the art would expect that, more likely than not, no naturally occurring DNA would share at least 92% sequence identity to SEQ ID NO:1 over the full length because the parts of the naturally occurring gene that are identical to SEQ ID NO:1 would be interrupted by introns that are not part of the cDNA sequence of SEQ ID NO:1. Thus the naturally occurring gene that encodes the polypeptide of SEQ ID NO:1 would only fall within the scope of part (b) of claim 36 if it has introns that comprise 8% or less of its sequence. If not, there is no naturally occurring DNA sequence identical to SEQ ID NO:1 over the entire length.

Thus, if part (b) of the claim is construed to being limited to DNA, the claim scope is likely a nullity and would add nothing to the claim.

On the other hand, if part (b) of claim 36 were construed to encompass both DNA and RNA, in addition to the ambiguities discussed above, it would present issues of enablement that have not been discussed on the record up to this point. That is, if the claim encompasses both DNA and RNA, and if the corresponding genomic DNA does not contain an anomalously small amount of intron DNA, the only "naturally occurring" polynucleotides that would be 92% identical to SEQ ID NO:1 over its entire length would be mRNAs (which are processed to excise introns).

Claim 36 is directed to an "isolated" polynucleotide, but the specification provides no guidance on how to isolate the particular mRNA corresponding to SEQ ID NO:1. Thus, if part (b) of claim 36 is construed to encompass both DNA and RNA, then for the reasons discussed herein, the DNA aspect is probably a nullity and it unclear whether the specification provides adequate guidance to enable those skilled in the art to make the mRNA that represents the remainder of the invention defined in part (b).

Finally, even assuming that part (b) of claim 36 were construed to encompass naturally occurring mRNAs that are at least 92% identical to SEQ ID NO:1, and assuming that the specification provides an enabling disclosure for such mRNAs, the scope of the claims would be unclear. The specification would appear to provide no guidance that would allow those skilled in the art to determine, with a reasonable degree of certainty, whether any of the sequences that are at least 92% identical to SEQ ID NO:1 occur naturally and, if so, which they would be. The only way to definitely fix the scope of the claims would be to compare SEQ ID NO:1 to all naturally occurring

sequences, clearly an impossible task. Thus, even if one were to ignore the various ambiguities herein, the metes and bounds of the claim are unclear.

Should prosecution of the application continue, the examiner should determine if a rejection of the claims 36-40 under 35 U.S.C. § 112, second paragraph, for indefiniteness or for lack of enablement based on the above, is appropriate.

CONCLUSION

In conclusion, we affirm the double patenting rejections. We affirm the rejection of claims 36-40 under 35 U.S.C. §112, first paragraph, for lack of written description of a naturally occurring polynucleotide sequence having greater than 92% sequence identity to the polynucleotide sequence of SEQ ID NO:1. We do not reach the lack of enablement and obviousness rejections. We do not reach the rejection of claims 36-40 under 35 U.S.C. §112, first paragraph, for lack of written description of variants (alleles) of SEQ ID NO:1.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED

William F. Smith
Administrative Patent Judge

Demetra J. Mills
Administrative Patent Judge

Eric Grimes
Administrative Patent Judge

) BOARD OF PATENT
) APPEALS AND
) INTERFERENCES

Foley and Lardner
Suite 500
3000 K. St. N.W.
Washington, D.C. 20007

dem